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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	§	ATTY DCKT NO: FWLPAT015US
Binie V. Lipps	§	
Frederick W. Lipps	§	
	§	
Serial No.: 10/047,945	§	Art Unit: 1644
	§	
Filed: January 14, 2002	§	Examiner: Szperka, Michael Edward
	§	
For: DIAGNOSIS AND TREATMENT FOR IMMUNOGLOBULIN E (IgE) IMPLICATED DISORDERS	§	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL

Submitted herewith in response to a decision from the Board of Appeals dated December 21, 2006 , please find enclosed:

(1) A Request for Reconsideration of the Decision (7 pages)
(2) A return post card.

Respectfully submitted:

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CERTIFICATION OF EXPRESS MAILING DATE

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Date 2/20/07

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REQUEST FOR REHEARING

Appellant requests Rehearing of the Decision of the Board, issued on December 21, 2006.

ARGUMENT

Claim 9 is representative of the claims on appeal and was reproduced on page 3 of the Decision. It reads as follows:

9. A method for reducing free serum
IgE in a human, comprising
administering to said human an effective amount of a peptide comprising at least the first four amino acids from the N-terminal of SEQ. ID. NO.: 2
to reduce serum level of free IgE in said human.

Claim 9 contains the recitations "a method for reducing **free** serum IgE" and "to reduce serum level of **free** IgE" (emphasis added).

It appears that the decision overlooks or misapprehends the requirement that the method of claim 9 is directed toward the reduction of "free" IgE.

On page 3 of the Decision, it is erroneously stated " . . . claim 9 is directed to a method of reducing the level of IgE in the serum . . . " This is not what has been claimed. It is the reduction of "free" IgE. Once bound by appellant's peptide, the IgE is no longer "free," although a reaction product between appellants' peptide and the IgE may be present.

On page 4 of the Decision it is stated "The examiner noted the experiments described in the specification purportedly showing that LT-10 reduces IgE levels, but concluded that the data do not support that conclusion" and on page 5 "We agree with the examiner. . ."

It is pointed out that reducing IgE levels is not what is set forth in claim 9. What is set forth is the reduction of "free" IgE levels. What is being agreed with is not directed toward what is set forth in claim 9.

On page 4 of the Decision it is stated "the experimental data in the specification do not show that LT-10 causes any reduction in the levels of IgE".

It is pointed out that this statement is not directed toward what has been set forth in claim 9, which is to reduce "free" IgE.

On page 4 of the Decision it is stated "The data do not show that the binding of LT-10 to IgE results in a reduction in the amount of IgE present."

It is pointed out that this statement is not directed toward what has been set forth in claim 9, which is the reduction of "free" IgE.

On page 4 of the Decision, it is stated "Appellants have pointed to no evidence showing the effect of LT-10 on serum IgE levels"

It is emphasized that what is claimed is "to reduce serum level of free IgE". The statement by the Board is not directed toward what is set forth in claim 9. Enablement for what is claimed is pointed to on page 4 of Appellants Brief and argued on page 8. In particular, Table 4, column LT-10 of appellants' specification shows declining free-IgE detection as measured in saliva as continued human in vivo LT-10 treatment continued. Enablement for the reduction of serum level of free IgE is fairly supported.

On page 6 of the Decision, first full paragraph, it is stated that "The specification shows that IgE can be measured in saliva but provides no evidence to show that the level measured in saliva is indicative of the level of free IgE in serum. . . . Thus, the evidence of record is not adequate to support the assertion that saliva levels of IgE provide an accurate measure of free serum levels of IgE."

This line of argument is raised for the first time in the Decision. It is not found in the Examiner's Answer, nor the Final Rejection, nor in the Office Action mailed January 24, 2005 which is incorporated into the Final Rejection, nor in any of papers of record, and appellant has not had the opportunity to address it before.

Under 37 CFR 41.50(a)(1), the Board is empowered to affirm or reverse the decision of the examiner on the grounds and on the claims specified by the examiner. Providing an additional line of argument to support a rejection from which appeal has been taken is outside of Board's authority in rendering a decision under 37 CFR 41.50(a)(1), as it is not based on grounds specified by the examiner, and withdrawal is requested.

It is pointed out that what is claimed is not measuring free IgE in saliva to "provide an accurate measure of free serum levels of IgE". What is claimed is a method for reducing serum level of free IgE. The data in the specification qualitatively supports an association between what was measured and what has been claimed. The specification states on page 1, line 15 that "A number of disorders and conditions are recognized by elevated levels of IgE". Tables 1 and 2 appearing on pages 11-12 of the specification show that free IgE as measured in the saliva of individuals suffering from a number of disorders and conditions was consistently higher than for normal individuals. The specification in the paragraph bridging pages 4 and 5 states that a monoclonal therapeutic has been proposed for lowering IgE in asthma patients. Table I shows that IgE as measured in the saliva of an asthma patient was 12 times normal. The specification in Experiment 1 at page 8 demonstrates that LT-10 reduces free IgE in saliva in vitro. The specification in Experiment 2 at page 8 demonstrates that LT-10 reduces free IgE in saliva in vivo. The specification in Experiment # 3 (page 13, line 20) reasonably shows that the administration of 2 mg/day of LT 10 steadily reduces serum levels of free IgE as measured in saliva over the course of treatment as shown in Table 4 appearing at page 15, ending at a level which is at about 1/3 of pretreatment levels. This result is furthermore graphically illustrated in Figure 1, which is described in the specification at page 18, line 19 through page 19, line 20, such description apparently being overlooked by the Board which states in Footnote 2 on page 3 that "the specification provides no explanation of what the figure shows." It is submitted that the disclosure is enabling for what has been claimed.

It is stated on page 6 of the decision, second full paragraph, that ". . .Appellants have pointed to no evidence showing that any fragments of SEQ ID NO: 2 smaller than 10 amino acids have an effect on IgE levels. . . .Thus, those skilled in the art would not assume, based on the state of the art, that fragments of LT-10 would also bind to IgE."

This line of argument is raised for the first time in the Decision. It is not found in the Examiner's Answer, nor the Final Rejection, nor in the Office Action mailed January 24, 2005 which is incorporated

into the Final Rejection, nor in any of papers of record, and appellant has not had the opportunity to address it before.

Under 37 CFR 41.50(a)(1), the Board is empowered to affirm or reverse the decision of the examiner on the grounds and on the claims specified by the examiner. Providing an additional line of argument to support a rejection from which appeal has been taken is outside of Board's authority in rendering a decision under 31 CFR 41.50(a)(1), and withdrawal is requested.

It is emphasized that claim 9 recites "to reduce serum level of **free** IgE". As pointed out on page 4 of Appellant's Brief on Appeal, "Most of the data in the specification is based on the species set forth above as SEQ ID NO: 1, referred to as LT-10 (for ten amino acids) in the specification. However, the specification states that all three versions that were made, LT-15, LT-10 and LT-5 have similar biological activity and are useful in this invention as are the peptides of intermediate length (page 3, lines 23-25)." In view of appellants statements regarding the operability of representative species within the scope of the claim, and the absence of any stated reasons for doubting the credibility of those statements, it is submitted that claim 9 is enabled over its full scope.

It is stated on page 6 of the decision ". . .we agree with the examiner that the specification does not provide adequate guidance to enable those skilled in the art to practice the claimed method - -reducing the serum level of IgE in a human by administering a peptide comprising the first four amino acids of SEQ ID NO: 2 --without undue experimentation."

It is pointed out that the claimed method is reducing serum level of "free" IgE, rather than "reducing the serum level of IgE". Enablement for what is claimed has been argued. It is also pointed out that claim 9 as examined was limited to SEQ ID NO: 2 (Final Rejection, page 2). The examiner never made a statement corresponding to " the specification does not provide adequate guidance to enable those skilled in the art to practice the claimed method - -reducing the serum level of IgE in a human by administering a peptide comprising the first four amino acids of SEQ ID NO: 2 --without undue experimentation" and this line of argument also fails to constitute a "grounds" under 37 CFR

41.50(a)(1) upon which the Examiner could be affirmed. What was examined and finally rejected was administering SEQ ID NO: 2. That SEQ ID NO: 2 binds to IgE is implicitly recognized at several places in the Decision, for example at page 5 "We agree with the examiner that, at best, the data show that LT-10 binds the same part of the IgE molecule that is bound by the antibody used in the ELISA test." As reasonably supported by the specification, the peptide binds some of the serum IgE when administered as recited in claim 9, and thereby reduces the level of free IgE. Enablement for fragments of LT-10 is as pointed out above.

It is stated on page 7 of the decision "there is no evidence that LT-10 reduces IgE levels. . ." (as pointed out above, this is not what is set forth in claim 9) "there is no evidence that the level of IgE measured in saliva corresponds to that in serum;" (as pointed out above, it is shown in the examples that continued LT-10 treatment steadily reduces free IgE as detected in saliva, supporting operability of claim 9, and the statement is furthermore a newly raised line of argument) "and there is no evidence that fragments of SEQ ID NO: 2 smaller than ten amino acids have any IgE binding activity" (as pointed out above, the specification states that LT-15, LT-10 and LT-5 were all made and have similar biological activity and are useful in the invention as are the peptides of intermediate length, and the statement is furthermore a newly raised line of argument).

It is stated on page 8 of the decision ". . .the specification provides inadequate evidence to show that any fragment of SEQ ID NO: 2 would have the effect of reducing the level of free serum IgE if administered to a human. Since the specification does not adequately enable any embodiment within the scope of the claims, it logically follows that it fails to enable practice of the full scope of the claims without undue experimentation." The conclusion does not follow from the premise, because it ignores SEQ ID NO: 2, which is all that was examined and finally rejected, and is the embodiment most fully supported by the specification. The statement furthermore constitutes an additional new line of argument not within the authorization of 37 CFR 41.50(a)(1) decision-making. Enablement for fragments of SEQ ID NO: 2 has been argued hereinabove.

As the Decision dated December 21, 2006 is based on neither the language of the claim as presented, or, alternatively, as examined and finally rejected, rehearing, reconsideration, and reversal of the rejection is requested.

Respectfully submitted,

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